K010325

JUN 2 5 2001

Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

510(K) Summary of Safety and Effectiveness

The Wako Autokit C4 test is an in vitro assay for the quantitative determination of C4 in serum.

Summary:
The Complement System is a plasma-based protein cascade, which functions as a highly regulated and effective immune barrier. The term "complement" dates from a turn of the century observation that certain heat labile components in human and animal sera enhanced or "complemented" its antibacterial activity. With the advent of advanced protein purification techniques in the 1960's, the Complement System was shown to be a true cascade of proteins comprised of more than thirty membrane bound and plasma components that work in concert to promote immune functions. The Complement System is comprised of four main protein cascades called the Classical, Alternative, Terminal, and the newly discovered Mannan Binding Lectin pathways. Complement has three primary functions including the enhancement of phagocytosis through opsonization and solubilization of immune complexes, lysis of target cells and microorganisms, and the release of anaphylatoxins.

C4 is central to all complement pathways and the most abundant circulating complement protein. Measurement of C4 (like C3 and C50) is an important index for the diagnosis of immune disease like lupus nephritis, allergics and inflammation. Because C4 is produced primarily in liver, C4 is also important in monitoring fulminant liver disease. [1,2] Autokit C4 is a highly specific immunoturbidimetric assay for quantitative measurement of C4 in human specimens.

Principle:
When a sample is mixed with reagents, C4 in the sample forms antigen-antibody complex with anti-C4 antibody (goat). The intensity of turbidity caused by the formation of the complexes is proportional to the amount of C4. By measuring the absorbance of the reaction mixture, the C4 amount in the sample is determined

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 0.5 mg/dL. In comparison studies against the predicate, a correlation coefficient of 0.9340 and a regression equation of $y = 1.12x - 3.08$ was obtained.

References:
1. Burtis, C.A. and Ashwood, E.R., Ed.: Tietz Textbook of Clinical Chemistry, 2nd Ed., Saunders, Philadelphia, 1994.
2. Lothar Thomas, M.D., Ed.: Clinical Laboratory Diagnostics.

June 20, 2001
Tonya Mallory, Executive Manager, Diagnostics
Wako Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Tonya Mallory
Diagnostics, Executive Manager
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, Virginia 23237

Re: K010325
Trade Name: Wako Autokit C4 and Immunoassay Calibrator
Regulation Number: 21 CFR § 866.5240 and 21 CFR § 862.1150
Regulatory Class: II Product Code: DBI
II JIX
Dated: April 16, 2001
Received: April 17, 2001

Dear Ms. Mallory:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT **Page 1 of 1**

510(k) Number: K010325
Device Name: Wako Autokit C4 and Immunoassay Calibrator

Indications for Use:

This reagent test system is used to measure complement component C4 in serum. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

In comparison studies against a commercially available nephelometric assay, a correlation coefficient of 0.9340 and a regression equation of $y = 1.12x - 3.08$ was obtained.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010325

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)